

Atty. Dkt. No. 071949-7002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Buechler, et al.

Title: METHODS AND COMPOSITIONS
FOR MEASURING BIOLOGICALLY
ACTIVE NATRIURETIC PEPTIDES
AND FOR IMPROVING THEIR
THERAPEUTIC POTENTIAL

Appl. No.: 10/645,874

Filing Date: 08/20/2003

Examiner: Unassigned

Art Unit: 1743

<p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on the date below.</p> <p><u>DIANE GARCIA</u> (Printed Name)</p> <p><u>Diane Garcia</u> (Signature)</p> <p><u>11-10-09</u> (Date of Deposit)</p>
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INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith a listing of the documents submitted to the U.S. PTO in parent application Serial No. 10/419,059, filed 04/17/2003. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date November 7, 2003

By Barry Wilson

FOLEY & LARDNER

Customer Number: 30542

Telephone: (858) 847-6722

Facsimile: (858) 792-6773

Barry S. Wilson

Attorney for Applicant

Registration No. 39,431

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of 8

Complete if Known

Application Number	10/419,059
Filing Date	04/17/2003
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-7001

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	5,480,792		Buechler et al.	Jan. 2, 1996	
	A2	5,525,524		Buechler et al.	June 11, 1996	
	A3	5,571,698		Ladner et al.	Nov. 5, 1996	
	A4	5,631,171		Sandstrom et al.	May 20, 1997	
	A5	5,679,526		Buechler et al.	Oct. 21, 1997	
	A6	5,719,060		Hutchens et al.	Feb. 17, 1998	
	A7	5,824,799		Buechler et al.	Oct. 20, 1998	
	A8	5,851,776		Valkirs	Dec. 22, 1998	
	A9	5,885,527		Buechler	March 23, 1999	
	A10	5,894,063		Hutchens et al.	Apr. 13, 1999	
	A11	5,922,615		Nowakowski et al.	July 13, 1999	
	A12	5,939,272		Buechler et al.	Aug. 17, 1999	
	A13	5,947,124		Buechler et al.	Sept. 7, 1999	
	A14	5,955,377		Maul et al.	Sept. 21, 1999	
	A15	5,985,579		Buechler et al.	Nov. 16, 1999	
	A16	6,019,944		Buechler	Feb. 1, 2000	
	A17	6,020,208		Hutchens et al.	Feb. 1, 2000	
	A18	6,027,942		Hutchens et al.	Feb. 22, 2000	
	A19	6,057,098		Buechler et al.	May 2, 2000	
	A20	6,107,623		Bateman et al.	Aug. 22, 2000	
	A21	6,113,855		Buechler	Sept. 5, 2000	
	A22	6,124,137		Hutchens et al.	Sept. 26, 2000	
	A23	6,143,576		Buechler	Nov. 7, 2000	
	A24	6,204,500		Whitehouse et al.	March 20, 2001	
	A25	6,225,047		Hutchens et al.	May 1, 2001	
	A26	6,268,144		Koster	July 31, 2001	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A27	WO	02/083913		Biosite Diagnostics, Inc.	Oct. 24, 2002		
	A28	WO	02/089657		Biosite, Inc.	Nov. 14, 2002		
	A29	WO	03/016910		Biosite, Inc.	Feb. 27, 2003		

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Sheet 2 of 8

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Applicati n Numb r	10/419,059
Filing Dat	04/17/2003
First Named Inv ntor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-7001

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A30	Bonow, R.O., "New insights into the cardiac natriuretic peptides." <i>Circulation</i> 93:1946-1950, (1996).	
	A31	Cagney and Emili, "De novo peptide sequencing and quantitative profiling of complex protein mixtures using mass-coded abundance tagging." <i>Nature Biotechnol.</i> 20: 163-170, (2002).	
	A32	Cannon <i>et al.</i> , "Invasive versus conservative strategies in unstable angina and non-Q-wave myocardial infarction following treatment with Tirofiban: Rationale and study design of the international TACTICS-TIMI 18 trial." <i>Am. J. Cardiol.</i> 82: 731-6, (1998)	
	A33	Cheng <i>et al.</i> , "A Rapid bedside test for B-type peptide predicts treatment outcomes in patients admitted for decompensated heart failure: A pilot study." <i>J. Am. Coll. Cardiol.</i> 37: 386-91, (2001).	
	A34	Cho <i>et al.</i> , "Natriuretic peptides and their therapeutic potential." <i>Heart Dis.</i> 1: 305-28, (1999).	
	A35	Cwirla <i>et al.</i> , "Peptides on phage: A vast library of peptides for identifying ligands." <i>Proc. Natl. Acad. Sci. USA</i> 87, 6378-82, (1990).	
	A36	Davidson <i>et al.</i> , "C-Type natriuretic peptide." <i>Circulation</i> 93:1155-9, (1996).	
	A37	Devlin <i>et al.</i> , "Random peptide libraries: A source of specific protein binding molecules." <i>Science</i> 249, 404-6, (1990).	

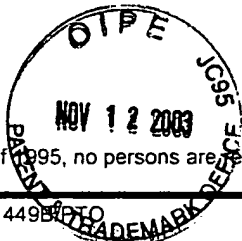
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Sheet 3 of 8

Compleat if Known

Application Number	10/419,059
Filing Date	04/17/2003
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-7001

NON PATENT LITERATURE DOCUMENTS

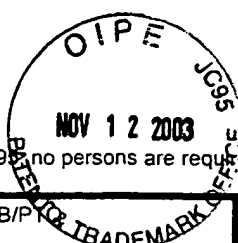
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A38	Fischer <i>et al.</i> , "Evaluation of a new, rapid bedside test for quantitative determination of B-Type natriuretic peptide." <i>Clin. Chem.</i> 47: 591-594, (2001).	
	A39	Gobinet-Georges <i>et al.</i> "Stability of brain natriuretic peptide (BNP) in human whole blood and plasma." <i>Clin. Chem. Lab. Med.</i> 38: 519-23, (2000).	
	A40	Hamm <i>et al.</i> , "Benefit of abciximab in patients with refractory unstable angina in relation to serum troponin T levels." <i>N. Engl. J. Med.</i> 340: 1623-9, (1999).	
	A41	Hartree, "Determination of protein: A modification of the lowry method that gives a linear photometric response." <i>Anal Biochem</i> 48: 422-427, (1972).	
	A42	Hunt <i>et al.</i> , "The role of the circulation in processing pro-Brain natriuretic peptide (proBNP) to amino-terminal BNP and BNP-32." <i>Biochem. Biophys. Res. Comm.</i> 214: 1175-83, (1995).	
	A43	Hunt <i>et al.</i> , "The amino-terminal portion of pro-Brain natriuretic peptide (Pro-BNP) circulates in human plasma." <i>Peptides</i> 18: 1475-81, (1997).	
	A44	Huse <i>et al.</i> , "Application of a Filamentous phage pVII fusion protein system suitable for efficient production, screening, and mutagenesis of F(ab) antibody fragments." <i>Journal of Immunology</i> , 140: 3914-3920, (1992).	

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Application Number	10/419,059
Filing Date	04/17/2003
First Named Inventor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-7001

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	A45	Issaq <i>et al.</i> , "SELDI-TOF MS for diagnostic proteomics." <i>Anal. Chem.</i> 75: 149A-155A, (2003).	
	A46	Issaq <i>et al.</i> , "The SELDI-TOF MS approach to proteomics: Protein profiling and biomarker identification." <i>Biochem. Biophys. Res. Commun.</i> 292: 587-92, (2002).	
	A47	Kalra <i>et al.</i> , "Myocardial production of C-Type natriuretic peptide in chronic heart failure." <i>Circulation</i> 107: 571-3, (2003).	
	A48	Lowry <i>et al.</i> , "Protein measurement with the folin phenol reagent." <i>J. Biol. Chem.</i> 193: 265, (1951).	
	A49	Merchant and Weinberger, "Recent advancements in surface-enhanced laser desorption/ionization-time of flight-mass spectrometry." <i>Electrophoresis</i> 21: 1164-67, (2000).	
	A50	Morrow <i>et al.</i> , "Cardiac troponin I for stratification of early outcomes and the efficacy of enoxaparin in unstable angina: A TIMI-11B substudy." <i>J. Am. Coll. Cardiol.</i> 36: 1812-7, (2000).	

Examiner
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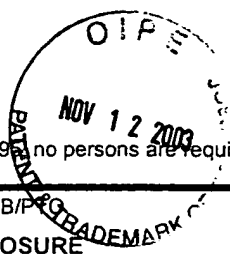
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				Application Number		10/419,059
				Filing Date		04/17/2003
				First Named Inventor		Kenneth F. Buechler
				Group Art Unit		Unassigned
				Examiner Name		Unassigned
(use as many sheets as necessary)				Attorney Docket Number		071949-7001
Sheet	5	of	8			

NON PATENT LITERATURE DOCUMENTS			
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	A51	Motwani <i>et al.</i> , "Plasma brain natriuretic peptide as an indicator for angiotensin-converting-enzyme inhibition after myocardial infarction." <i>Lancet</i> 341: 1109-13, (1993).	
	A52	Murdoch <i>et al.</i> "Brain natriuretic peptide is stable in whole blood and can be measured using a simple rapid assay: Implications for clinical practice." <i>Heart</i> 78: 594-7, (1997).	
	A53	Ng and Ilag, "Biomedical applications of protein chips." <i>J. Cell Mol. Med.</i> 6: 329-340, (2002).	
	A54	Norman <i>et al.</i> "Degradation of brain natriuretic peptide by neutral endopeptidase: Species specific sites of proteolysis determined by mass spectrometry." <i>Biochem. Biophys. Res. Commun.</i> 28: 175: 22-30, (1991).	
	A55	Prickett <i>et al.</i> , "Identification of amino-terminal Pro-C-Type natriuretic peptide in human plasma." <i>Biochem. Biophys. Res. Commun.</i> 286:513-7, (2001).	

Examiner Signature	Date Considered
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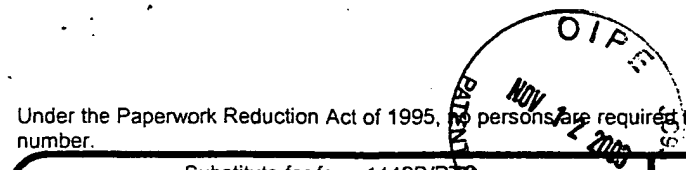
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Group Art Unit		Unassigned			
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	A56	Ridker <i>et al.</i> , "Inflammation, pravastatin, and the risk of coronary events after myocardial infarction in patients with average cholesterol levels." <i>Circulation</i> 98: 839-44 (1998).		
	A57	Scott and Smith, "Searching for peptide ligands with an epitope library." <i>Science</i> 249, 386-88, (1990).		
	A58	Shimizu <i>et al.</i> , "Degradation of human brain natriuretic peptide (BNP) by contact activation of blood coagulation system." <i>Clin. Chem. Acta</i> 305: 181-6, (2001).		
	A59	Shimizu <i>et al.</i> , "Molecular forms of human brain natriuretic peptide in plasma." <i>Clin. Chem. Acta</i> 316: 129-35, (2002).		
	A60	Smith <i>et al.</i> , "Delayed metabolism of human brain natriuretic peptide reflects resistance to neutral endopeptidase." <i>J. Endocrinol.</i> 167: 239-46, (2000).		
	A61	Tateyama <i>et al.</i> , "Concentrations and molecular forms of human brain natriuretic peptide in plasma." <i>Biochem. Biophys. Res. Commun.</i> 185:760-7, (1992).		

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	A62	Trindade and Rouleau, "Vasopeptidase inhibitors: potential role in the treatment of heart failure." <i>Heart Fail. Monit.</i> 2: 2-7, (2001).	
	A63	Troughton <i>et al.</i> , "Treatment of heart failure guided by plasma aminoterminal brain natriuretic peptide (N-BNP) concentrations." <i>Lancet</i> 355: 1126-30, (2000).	
	A64	Van Veldhuisen <i>et al.</i> , "High-Versus low-dose ACE inhibition in chronic heart failure: A double-blind, placebo-controlled study of Imidapril." <i>J. Am. Coll. Cardiol.</i> 32: 1811-8 (1998).	
	A65	Venugopal, "Cardiac natriuretic peptides – hope or hype?" <i>J. Clin. Pharm. Ther.</i> 26: 15-31, (2001).	
	A66	Ward <i>et al.</i> , "Binding activities of a repertoire of single immunoglobulin variable domains secreted from <i>Escherichia coli</i> ." <i>Nature</i> 341:544-546, (1989).	

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Sheet 8 of 8

Compleat if Known

Application Number	10/419,059
Filing Dat	04/17/2003
First Nam d Inv ntor	Kenneth F. Buechler
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	071949-7001

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A67	Wilson, "Simplified conjugation chemistry for coupling peptides to F(ab') fragments; autologous red cell agglutination assay for HIV-1 antibodies." <i>J. Immunol. Methods</i> 175:267-273, (1994).	
	A68	Wright et al., "Proteinchip® surface enhanced laser desorption/ionization (SELDI) mass spectrometry: a novel protein biochip technology for detection of prostate cancer biomarkers in complex protein mixtures." <i>Prostate Cancer and Prostatic Diseases</i> 2: 264-76, (1999).	
	A69	Yarmush, "Coupling of antibody-binding fragments to solid-phase supports: site-directed binding of F(ab') ₂ fragments." <i>J. Biochem. Biophys. Methods</i> 25:85-97, (1992).	

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